PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

F B RICE & CO
605 Darling Street
BALMAIN NSW 2041

RECEIVED
17 OCT 2003
F. B. RICE & CO.

PCT

WRITTEN OPINION
(PCT Rule 66)

	Date of mailing *(day/month/year)* 16 OCT 2003
Applicant's or agent's file reference 115117	**REPLY DUE** within **TWO MONTHS** from the above date of mailing

International Application No.	International Filing Date *(day/month/year)*	Priority Date *(day/month/year)*
PCT/AU03/00828	27 June 2003	28 June 2002

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. [7] H04R 25/00; A61N 1/05

Applicant
COCHLEAR LIMITED et al

1. This written opinion is the **FIRST** drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:.

I	[X]	Basis of the opinion
II	[ ]	Priority
III	[X]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[X]	Lack of unity of invention
V	[X]	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

3. The **FINAL DATE** by which the international preliminary examination report must be established according to Rule 69.2 is:
28 October 2004

The applicant is hereby **invited to reply** to this opinion.

When? See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established.
If no response is filed by 1 month before the Final Date, the international preliminary examination report will be established on the basis of this opinion.
Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least **3 months before the Final Date** by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*.
For an informal communication with the examiner, see Rule 66.6.

Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	**MANISH RAJ** Telephone No. (02) 6283 2175

WRITTEN OPINION

International application No.
PCT/AU03/00828

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*

WRITTEN OPINION

International application No.
PCT/AU03/00828

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 27 - 35

because:

☐ the said international application, or the said claim Nos. relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. **27 - 35, as no required additional search fees were paid by the applicant. Consequently, the international search report was restricted to the invention first mentioned in the claims. Also, refer to item IV for lack of unity of invention.**

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

WRITTEN OPINION

International application No.
PCT/AU03/00828

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Preliminary Examining Authority has found that there are ***three (3)*** different inventions as follows:

1. Claims 1-26 are directed to "*a implantable electrode array for insertion*" including the following features:

(i) an elongate carrier having a proximal end and a distal end,
(ii) a plurality of electrodes supported by the carrier,
(iii) a stabilising or anchoring means extending outwardly from the elongate carrier, and
(iv) the collar means having an abutment surface to abut at least a portion of the surface of the cochlea and
prevent movement of the carrier following insertion of the array into the cochlea.

It is considered that "***stabilising collar means having an abutment surface to prevent movement of the carrier following insertion of the array into the cochlea***" comprises a first "special technical feature".

2. Claims 27-32 are directed to "*an implantable component of a cochlear implant system*" including the following features.

(i) a housing for a stimulator unit,
(ii) a first elongate electrode assembly,
(iii) a second elongate electrode assembly, and
(iv) wherein only one of the first and second electrode assemblies in insertable into cochlea at any particular
time.

It is considered that "***only one of the first and the second electrode assemblies is insertable into the cochlea at any particular time***" comprises a second "special technical feature".

Continued on the supplement sheet.....

3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. **1 - 26**

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	----	YES
	Claims	**1 - 26**	NO
Inventive step (IS)	Claims	----	YES
	Claims	**1 - 26**	NO
Industrial applicability (IA)	Claims	**1 - 26**	YES
	Claims	----	NO

2. Citations and explanations

CITATIONS:

D1: US 6498954B1

D2: US 6308101B1

D3: US 6259951B1

D4: US 6163729A

D5: WO 00/71063A1

D6: US 6119044A

D7: WO 97/26943A1

D8: WO 96/31087A1

NOVELTY (N) Claims 1-26:

The document D1 discloses all the essential features of Claims 1-26. Refer to the whole document with specific reference to column 5, line 41 to column 6, line 7 and figures 5 and 6 where it discloses that a depth marker is provided to indicate the proper insertion depth of the electrode array.

The document D2 discloses all the essential features of Claims 1, 15, 22 and 26 at least. Refer to figure 6 where it discloses a stabilising collar means to abut at least a portion of surface of the cochlea and substantially prevent movement of the carrier following insertion of the array into the cochlea.

The document D3 discloses all the essential features of Claims 1, 15, 22 and 26 at least. Refer to figure 1 where it discloses a stabilising collar means to abut at least a portion of surface of the cochlea and substantially prevent movement of the carrier following insertion of the array into the cochlea.

The document D4 discloses all the essential features of Claims 1-26. Refer to the whole document with specific reference to column 6,.line 65 to column 7, line 17 and figure 2 where it discloses an offset to prevent the electrode from being inserted too deep into the cochlea.

The document D5 discloses all the essential features of Claims 1-26. Refer to the whole document with specific reference to page 6, lines 1-10 and figures 7a-7d where it discloses a ring to indicate insertion depth of the array into the cochlea and for holding the array during the insertion.

Continued on the supplement sheet.....

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of IV (Lack of Unity of Invention)...

3. Claims 33-35 are directed to "*a method of operating a cochlear implant system*" including the following features:

(i) a housing for a stimulator unit,
(ii) an elongate electrode assembly,
(iii) the assembly having a proximal end and a distal end and comprising of a plurality of electrodes,
(iv) one or more of the electrodes closer to the proximal end being adapted to provide stimulation to the basilar region of the cochlea,
(v) one and more of the electrodes relatively closer to the distal end being adapted to provide stimulation to a location beyond the first basal turn of the cochlea, and
(vi) when recipient is unable to hear relatively high frequency sounds only activating those one or more electrodes adapted to provide stimulation to the basilar region of the cochlea.

It is considered that "***one or more of the electrodes closer to the proximal end being adapted to provide stimulation to the basilar region of the cochlea and one and more of the electrodes relatively closer to the distal end being adapted to provide stimulation to a location beyond the first basal turn of the cochlea and activating those one or more electrodes***" comprises a third "special technical feature".

Since the above mentioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of V (*Reasoned statement with regard to novelty, inventive step or industrial applicability*)

The document D6 discloses all the essential features of Claims 1-26. Refer to the whole document with specific reference to column 10, lines 32-39 and figures 3, 4, 15 & 16 where it discloses an offset portion that marks the beginning of the electrode array and facilitates insertion of the electrode array into scala tympani duct of the cochlea.

The document D7 discloses all the essential features of Claims 1, 15, 22 and 26 at least. Refer to page 10, lines 10-13 and figure 1 where it discloses a tab provides a marker for indicating the insertion of the electrode array to an intended depth.

The document D8 discloses all the essential features of Claims 1-26. Refer to the whole document with specific reference to page 28, lines 10-31 and figures 20 & 21 where it discloses a fitting which is located just outside the entrance to the cochlea for locking the electrode carrier assembly in place with the cochlea.

INVENTIVE STEP (IS) Claims 1-26:

As above

INDUSTRIAL APPLICABILITY (IA) Claims 1-26:

Claims 1-26 are considered to have industrial applicability.